

**UNIVERSITY OF WASHINGTON
CONSENT FORM
Parent Consent Form/Adolescent Assent Form**

KING COUNTY ASTHMA PROGRAM FOR CHILDREN

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Researchers' statement – ages 7 through 17 and caregiver

We are asking you or your child to be in a research study. ("You" refers to either a child between the ages of 7-17 or the caregiver of a child 3-6 years of age. The purpose of this consent form is to give you the information needed to help you decide whether to be in the study

or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called “informed consent.” We will give you a copy of this form for your records.

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PURPOSE OF THE STUDY

You are being asked to take part in a research study. It is up to you if you want to take part.

The purpose of this research study is to improve the health of children who have asthma. In this study a community health worker (CHW) will visit you at home to show you how to monitor and control your asthma symptoms and help to identify things that may make the your asthma worse. They will also work you to make the home safer and will provide supplies to help you keep your home healthy (vacuum cleaners, mattress and pillow covers, HEPA air filters (as needed), storage containers for food items and cleaning supplies.

The study will compare 200 enrolled participants receiving home visits to past participants who received home visits.

We expect that all children who take part in this study will benefit directly. Taking part in the study may also benefit other children in the future who have asthma. We hope the information gained from this study will help find new ways to provide better asthma education and care for children who have asthma that is cost effective.

We expect about 200 children who live in the King County area will take part in this study. The study will last one year. Children who have not well controlled asthma will be asked to take part.

STUDY PROCEDURES

Enrolling in the Project

Project staff has confirmed with your medical provider that you have asthma and are eligible to take part in this study. You will be asked questions about your home life and medical condition. You may refuse to answer any questions or items in any test our questionnaire, inventory or interview. This will not keep you from participating in the study.

Before enrolling in the study, you will be asked to complete an enrollment interview. The interview will take place in your home and conducted by a community health worker.

This appointment will last about 2 ½ hours, and include these things:

- Questions about your asthma (symptoms, how asthma affects your life, and what medicines you use).

- Questions about your home environment and the CHW will walk around your house and look for things that would trigger your asthma.

The study will last for one year, though you are free to withdraw at anytime. During the year, you will receive home visits and phone calls by a project community worker. Also, you will be contacted by phone 6, 12 and 18 months from enrollment by project staff to answer questions about your asthma. It will take about 15 minutes for the call. You will be given a \$10 Safeway gift card for completing each surveys.

In-Home Check Up

During the project, all will receive an in-home check up by a project CHW at the start of the project. This visit will take up to 2 1/2 hours. The CHW will walk around your home with you to look for things such as mold or pests that might make your asthma worse, and ask you about things you might do to get rid of things that can set off asthma. During the home check-up, staff may take pictures to document housing conditions (not to include people). Pictures will be used for training purposes, and to describe the project. If you do not want pictures to be taken, you are free to say so and we will NOT take your picture.

You will receive one assessment home visit and up to three follow-up home visits from a project community health worker during the study. This person will work with you to develop a plan to make help you control your asthma better and encourage you to actively carry out the plan. Following this plan may take a couple of hours or more of your time each week. The project worker will bring you information to help you with your plan. You will receive the special tools that may make your home healthier, including a HEPA vacuum cleaner, HEPA filter (if appropriate) and cleaning supplies (bucket, vinegar, baking soda, and scouring pad), allergy control bed covering, storage containers for food items, medicine box free of charge. You will receive all of your supplies by the third follow-up visit. It might be useful to make some home improvements and, if you would like, we can help you contact your landlord about them. Each visit will last about an hour.

Completing the Project

The research project will be over after you complete the Exit Interview and the Exit In-Home Check Up and the phone survey conducted 18 months from enrollment. These will take place at 18 months from the time you enrolled.

Exit Interview

The Exit Interview and home check up will take place in your home, just like the enrollment interview. It will last about 1 ½ hours and be much like the enrollment visit.

RISKS, STRESS, OR DISCOMFORT

Interviews

You may find some of the questions asked during the interview to be embarrassing. For example we will ask you how often you clean your home and whether you had any problems with cockroaches. You are free to not answer any of the questions.

Pest Control

If you have problems with roaches, the community health worker will help you by placing a gel with roach bait in places where roaches might be found but where children can't get to it. The gel contains a chemical (pesticide) that kills roaches but can harm people if they eat large amounts of it or get it on the skin or eyes. Only small amounts will be used in your home. If you don't want to use the bait, you don't have to and can still take part in the study.

Other Considerations

If project staff sees clear signs of child abuse or neglect and/or vulnerable children abuse or neglect, they are required by law to report this to Child Protective Services or Adult Protective Service.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to participate, you can continue to use your regular healthcare provider.

BENEFITS OF THE STUDY

Children participating in the study may have a number of benefits. These benefits might include increased asthma self-management skills, asthma control support, and supplies that may make your home healthier. Both groups will receive these benefits

If this project shows that home visits improve asthma control, this project can be used to help community healthcare providers and other asthma programs promote access to home visits for all children with asthma. Society will benefit from improved health of its members and potentially decreased costs for caring for people with asthma.

OTHER INFORMATION

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Taking part in research is voluntary. You may choose not to take part and may withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect the care that you or receive. All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Participation will be kept confidential, within the limits of the law. A copy of this signed consent form will be put into your participant file. Your name will be separated from any information collected about you and your house. No names or other identifying information will be used in any publications or presentations that may result from this study. Access to study data that identifies participants will be limited to the project, your medical provider, and the funding agency, the National Institute of Environmental Health Sciences (NIEHS). Data from individuals (such as questionnaires) will be kept until December 2017.

This project is funded by the Centers for Disease Control. The study procedures will be done at no cost to you. You will be paid for completing each of the study phone interview:

Phone Interview at 6 months:	\$10 gift card after completing the interview
Phone interview at year 1:	\$10 gift card after completing the interview
Phone interview at 18 months:	\$10 gift card after completing the interview
Total:	\$30.00

You will also receive the following equipment free of charge as a result of taking part in the study: a vacuum cleaner, cleaning supplies, allergy control mattress covers and pillow covers, storage containers for food items, medicine box and HEPA filters.

In the event of a physical injury as a direct result of participating in this study, medical care at routine cost will be available to you. The University of Washington will pay up to \$10,000 to treat injury or illness caused by the study. No other compensation is available. Public Health Seattle King County does not have a program for monetary or other forms of compensation for research-related injury.

If any problems or questions come up while taking part in the study, you can call Miriam Philby, Project Manager, at the Public Health – King County. Her phone number is 206-263-8235.

For questions about your rights as a research participant, contact the University of Washington Institutional Review Board (IRB) at (206) 543-0098. The IRB is a committee that reviews the research to be sure that your rights as a research participant are protected.

Printed name of study staff obtaining consent	Signature	Date
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Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date
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When subject is not able to provide informed consent

Printed name of representative	Signature of representative	Date
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Relationship of representative to subject

Copies to: Researcher
 Subject
 Subject's Participant Record

Printed name of study staff obtaining consent	Signature	Date
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Printed name of subject	Signature of subject	Date
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When subject is a minor:

Printed name of parent	Signature of parent	Date
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When subject is not able to provide informed consent

Printed name of representative	Signature of representative	Date
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Relationship of representative to subject

Copies to: Researcher
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